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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,785	02/16/2001	Tadamitsu Kishimoto	046124-5042	1146

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/26/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,785

Applicant(s)

KISHIMOTO ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Response to Amendment

The Amendment filed June 11, 2003 (Paper No. 18) in response to the Office Action of is acknowledged and has been entered.

New Claims 28-31 were added.

Claims 1-23, and 25-27 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 24, and 28-31 are pending and are currently under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

Applicants acknowledge (Paper No. 18, page 5) that the Disclosure Statements filed in March and September of 2002 were not intended to include a PTO 1449 form.

Subsequently, an information disclosure statement (IDS) was submitted on 05-23-03 (Paper No. 17) and has been considered; a copy of which is attached herein. Duplicate references have been lined through.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, and 28-31 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a substance that inhibits the action of CXCR4 in a mammal in need thereof, “**wherein said substance is not dexamethasone**” has no clear support in the specification and the claims as originally filed. Hence, this is a new matter rejection. Newly added claims 28-31 are included in this rejection because the scope of the claimed subject matter includes those substances that are not dexamethasone. Applicants argue (Paper No. 18, page 4) that support for the amendment to claim 24 is found, *inter alia*, in original Claim 24; on page 4, lines 6-7; and, page 19, lines 10-22. The suggested support is not found persuasive because there is nothing in the specification that teaches or specifically suggests that the substance that inhibits the action of CXCR4 in a mammal cannot include dexamethasone.

Claims 28-29 are rejected under 35 U.S.C. 112, second paragraph, for reciting “based on”. The phrase “based on” is indefinite language because it is not clear whether the limitations following the phrase are indeed part of the claimed invention. Hence, it cannot be determined which substances infringe or do not infringe on the claimed subject matter.

Claim 28 is further rejected under 35 U.S.C. 112, second paragraph, for reciting “the ligand (SDF-1)”. Are the claims limited to SDF-1? As written, it cannot be determined if SDF-1 is merely one example of many ligands or if the claims are solely directed to SDF-1.

Rejections Withdrawn:

The rejection of Claim 24 as being anticipated by Arisawa *et al.* (Ann.Surg.Oncol, March 1995, Vol.2, No.2, pages 114-120) has been withdrawn. However, if in responding to this action, Applicant's amend Claim 24 to cancel recitation of "wherein said substance is not dexamethasone", the rejection will be reinstated.

Rejections Maintained:

Claim 24 remains rejected **and Claims 28-31** are rejected under 35 U.S.C. 102(b) as being anticipated by Honjo *et al.* (US Patent No. 5,563,048, 1994) for the reasons of record in Paper No. 18, page 4-5, and for the reasons set forth below as further evidenced by Signoret *et al.* (J. Cell Biol., Vol. 193, No. 3, 1997, IDS # 5, of Paper No. 17).

Honjo *et al.* teach a method for suppressing vascularization comprising administering a substance that inhibits the action of CXCR4 in a mammal in need thereof, wherein said substance is not dexamethasone for the reasons of record. As for the newly added claims, the teachings of Honjo *et al.* include pharmaceutical compositions of SDF-1 polypeptides and or antibodies thereof, in association with a pharmaceutically acceptable diluent and or carrier (column 2, lines 64+). These substances encompass substances that are based on the inhibition of the binding between SDF-1 and the receptor CXCR4 and substances based on the inhibition of signaling from CXCR4 to nuclei. These pharmaceutical compositions further encompass

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substances that inhibit the expression of CXCR4, itself as evidenced by Signoret *et al.* (J. Cell Biol., Vol. 193, No. 3, 1997, IDS # 5, of Paper No. 17). Signoret *et al.* teach (page 659 and 662, 1st columns) that cell surface CXCR receptors are rapidly down-modulated following addition of SDF-1. The specification identifies substances that inhibit the expression of CXCR4 as those that include substances that make CXCR4 disappear on cells. "A specific example of the substance that apparently makes CXCR4 disappear on cells is a substance that includes down-regulation of CXCR4" (page 19, lines 10+). Thus, the SDF-1 ligands, as taught by Honjo *et al.* encompass those substances that inhibit the expression of CXCR4 itself. The teachings of Honjo *et al.* further encompass (column 5, lines 45+) a substance that inhibits the expression of SDF-1 itself because the reference teaches that SDF-1 ligand DNA may be used therapeutically for the treatment of genetic diseases by inhibiting the expression of the polypeptide by antisense DNA or RNA.

In response to the first office Action (Paper No. 16), Applicants appear to argue (Paper No. 18, page 6) that because the reference does not specifically teach the pharmacological activity of the SDF-1 ligand polypeptides, the reference lacks a case for inherency. This argument has been considered but is not found persuasive. Although the prior art does not specifically teach the pharmacological activity of the SDF-1 ligand, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Further, granting a patent on the discovery of an unknown but inherent function would remove from the public that

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which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Applicants further appear to argue (Paper No. 18, pages 6-7) that the listing of therapeutic uses for the SDF-1 ligands is exhaustive and is not based on any tested or demonstrated activities. Thus, applicants argue, the reference is deficient in teaching the alleged utility of the polypeptides as possible therapeutics for suppressing vascularization. This argument has been considered but is not found persuasive. First, the reference is a US Patent, which is relevant as prior art for all that it teaches. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.” In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Secondly, it appears that applicants are arguing that the prior art is *inoperable*. However, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, *inoperability of the prior art*, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

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All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN
August 24, 2003

Gary B. Nickol